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December 1, 1999

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General Orthopaedic Surgery

Trauma and Fracture Care

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Total Joint

Replacement

Arthroscopy

Sportsmedicine

Hand Surgery/ Microsurgery

Spine Surgery

Foot and Ankle Surgery

Pediatric Orthopaedics

I'm submitting my comments regarding the regulation of allograft tissue and allograft bone implants which in my hands as well as in many of the perviewed papers show a far superior result than using metallic implants. Bone banks which typically are not for profit do not have the resources or expertise to be able to do an FDA clinical trial. This would significantly curtail the use of allograft bone implantation. The use of such bone is actually quite beneficial for patient care. It seems as if it is more of an industry driven assessment. Those who have metallic implants are placing pressure and questioning the efficacy of allograft implants because they would much rather see such implants go through rigorous assessment so that there would be more of a chance for industry leaders in metal

implants to gain an edge.

Sincerely,

Allen Carl, M.D.

Professor of Surgery Division of Orthopaedics

Scoliosis

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